K 121938

510(k) SUMMARY

Dornier's Medilas H Laser Fibers

AUG 1 2012

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Dornier MedTech America
1155 Roberts Blvd.
Kennesaw, GA 30144

Phone: 770-514-6163
Fax: 770-514-6291
Date Prepared: June 28, 2012

Contact Person: John Hoffer

Phone: 770-514-6163

Name of Device and Name/Address of Sponsor

Medilas H RFID Laser Fibers
1155 Roberts Blvd.
Kennesaw, GA 30144

Common or Usual Name

Holmium Laser Fibers

Classification Name

Laser Instrument, (Accessory); Product Code GEX

Predicate Devices

Dornier Medilas H Laser Fiber K022544
Accuflex Laser Fibers K050108
Lumenis SlimLine Fibers K011703

Purpose of the Special 510(k) notice.

The Medilas H RFID Laser Fiber is a modification to Dornier's currently cleared Dornier Medilas H Laser Fiber K022544.

Intended Use

Dornier's Medilas H RFID Laser Fibers are intended to be used as an accessory for the Dornier Medilas H Holmium Laser ("Laser"). This laser is intended for cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or for open surgery for contact or non-contact surgery with or without a handpiece for use in incision/excision, vaporization, ablation and coagulation of soft tissue. The Laser is indicated for use in medicine and surgery, in the following medical specialties:
Arthroscopy, Urology, Lithotripsy, Pulmonology, Gastroenterology, Gynecology, ENT, General Surgery

Substantial Equivalence

Dornier's Medilas H RFID Laser Fibers has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate devices. The minor differences in the technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the Dornier Medilas H RFID Laser Fibers are as safe and effective as the listed predicates. Thus, the Dornier Medilas H RFID Laser Fibers are substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 1 2012

Dornier Medtech America, Incorporated
% Mr. John Hoffer
1155 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K121938
Trade/Device Name: Dornier Medilas H RFID Laser Fibers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 28, 2012
Received: July 02, 2012

Dear Mr. Hoffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 121938

Device Name: Dornier Medilas H RFID Laser Fibers

Indications for Use:

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Arthroscopy
Urology
Lithotripsy
Pulmonology
Gastroenterology
Gynecology
ENT
General Surgery

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(Division Sign-Off) for mxm
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121938

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)